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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/389,318	09/03/1999	OSAMU SUZUKI	001560-372	5287

21839 7590 06/14/2002

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ALEXANDRIA, VA 22313-1404

[REDACTED] EXAMINER

MARX, IRENE

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1651

DATE MAILED: 06/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/389,318	Applicant(s) Suzuki et al.
	Examiner Irene Marx	Art Unit 1651
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
<ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 		
Status		
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>May 20, 2002</u>		
2a) <input type="checkbox"/>	This action is FINAL .	2b) <input checked="" type="checkbox"/> This action is non-final.
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.		
Disposition of Claims		
4) <input checked="" type="checkbox"/> Claim(s) <u>1, 3-8, 10-15, and 17-33</u> is/are pending in the application.		
4a) Of the above, claim(s) <u>8, 10-15, and 17-30</u> is/are withdrawn from consideration.		
5) <input type="checkbox"/>	Claim(s) _____	is/are allowed.
6) <input checked="" type="checkbox"/>	Claim(s) <u>1, 3-7, and 31-33</u>	is/are rejected.
7) <input type="checkbox"/>	Claim(s) _____	is/are objected to.
8) <input type="checkbox"/>	Claims _____	are subject to restriction and/or election requirement.
Application Papers		
9) <input type="checkbox"/> The specification is objected to by the Examiner.		
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).		
*See the attached detailed Office action for a list of the certified copies not received.		
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.		
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)		
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____		
4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____		
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)		
6) <input type="checkbox"/> Other: _____		

Since this application is eligible as a Continued Prosecution Application under 37 CFR 1.153(d), the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.153(b). Applicant's submission on May 20, 2002 has been entered.

Claim 1, 3-7, and 31-33 are being examined on the merits. Claims 8, 10-15, and 17-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 31-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the production of 7 g/l arachidonic acid under the conditions of the claim designated invention with any strain of the genus *Mortierella* or any member of the genus *Mortierella*, subgenus *Mortierella*.

Applicants rely on Example 2 as basis and support for at least some of the conditions. It is noted that the example is directed to one particular strain of *Mortierella*. Please see *PurduePharma v. Faulding* 56 USPQ2d 1481 (CA FC 2000) for a discussion related to a failure to describe a claimed generic concept in the narrative portion of the specification, but rather basing support on limitations in examples.

Therefore, this material raises the issue of new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 32 are substantial duplicates.

Claim 31 is vague and indefinite in that the medium wherein the member of *Mortierella* has the ability to produce about 7 g/l is not defined with sufficient specificity.

The claims are vague, indefinite and confusing, it that is it unclear which strains of fungi are properly classifiable as members of the genus *Mortierella*, subgenus *Mortierella*.

Claims 1-7 and 31-33 are incomplete in the absence of a recovery step for the product produced.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31-32 are/remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kyle for the reasons as stated in the last Office action and the further reasons below.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that Kyle discloses a maximum productivity of 5.3 g/L in 10 days of culturing. Yet all the invention as claimed requires is "the ability" to produce arachidonic acid of at least about 7 g/l. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains differ and, if so, to what extent in their ability to produce arachidonic acid, from the strains discussed in the references.

Therefore the rejection is deemed proper and it is adhered to.

Claims 1, 3-7 and 31-33 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle for the reasons as stated in the last Office action and the further reasons below.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that Kyle does not render the invention as claimed obvious because the reference discloses a maximum productivity of 5.3 g/L in 10 days of culturing and the reference does not disclose or suggest a process of production of arachidonic acid resulting in the production of at least 7 g/L . The arguments by counsel that the results of Example 2 can be extrapolated to any strain of *Mortierella* having resistance to a carbon source of high concentration are noted. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence. The basis for the conclusionary statement that the strain of Kyle does not have the

carbon source resistance is uncertain. The argument is puzzling since the strain is clearly “resistant” to 8% and 10% glucose, which is deemed a “high concentration” of carbon.

With respect to 1 vvm aeration, it is noted that the reference uses 0.5 vvm. The adjustment of process conditions for optimization purposes of conditions identified as result-effective variables cited in the references, such as the extent of aeration of an aerobic fungus, would have been prima facie obvious to a person having ordinary skill in the art. There is nothing on the record to suggest that the increased aeration provides for unexpected results.

In addition, and as noted in the last Office action, the only strain shown to have the required ability and, in fact, to produce the touted amount of arachidonic acid is the deposited strain SAM 2197(See, e.g.,Table 1) using glucose as carbon source in conjunction with yeast extract and under specific process conditions. There is no clear correlation between the “resistance to a carbon source of high concentration” and the productivity claimed. See also the rejection under new matter.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Claim 6 would be allowable upon resolution of all issues under 35 U.S.C § 112, since it is directed to a process of production of arachidonic acid by strain *Mortierella* SAM 2197 in amounts of at least 7 g/l in 5-10 days, which is neither taught nor fairly suggested by the prior art. One of ordinary skill in the art would not be motivated to use this particular strain in a process of production of arachidonic acid as claimed.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx

Irene Marx
Primary Examiner
Art Unit 1651